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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/499,526 02/10/00 LU K ONV.058.01

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HM22/1214

EXAMINER

DEBERRY, R

ART UNIT

PAPER NUMBER

1647

7

DATE MAILED:

12/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/499,526

Applicant(s)

LU ET AL.

Examiner

Regina M. DeBerry

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/9/00.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Status of Application, Amendments and/or Claims

Applicant's preliminary amendments of 9 November 2000 (Paper No. 6)
for the substitute sequence listings have been entered in full.

DETAILED ACTION

Election/Restrictions

1. The pending claims are replete with errors confusing the nature of the claimed inventions. For example, there are numerous instances of lack of antecedent basis for terms, dependent claims fail to refer to previous claims in the alternative, and terms such as "PYY agonist" and "PYY Therapeutic", among others are undefined. The claims have been given the broadest, reasonable interpretation for the purpose of the following restriction requirements. It is noted in claim 29, that "the method of claim 23,24, or 24" should read "the method of claim 23,24, or 25".

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to method for contacting pancreatic cells with a PYY peptide homologous to SEQ ID 1, classified in class 530, subclass 300.
- II. Claims 1-6,8,9, drawn to a method for contacting pancreatic cells with a peptidomimetic, classification depends on structure of peptidomimetic.
- III. Claims 1-6,10-12 drawn to a method for contacting pancreatic cells with non-peptidyl agonist, classification depends on structure of non-peptidyl agonist.

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- IV. Claims 13-23,28-33,39,42,43,45,46,50 drawn to a method for administering PYY Therapeutic, classification depends on structure of PYY Therapeutic.
- V. Claims 24,28-32,39, 42,43,50 drawn to a method for administering an antagonist of a PYY antagonist, classification depends on structure of the antagonist of a PYY antagonist.
- VI. Claims 25-27, 28-32,39,42,43,50 drawn to a method for administering cells and a PYY Therapeutic, classification depends on structure of PYY Therapeutic.
- VII. Claims 34,37 drawn to a method for administering an organic therapeutic, classification depends on structure of organic therapeutic.
- VIII. Claims 34,37,39,42,43,50 drawn to a method for administering an organic antagonist, classification depends on structure of organic antagonist.
- IX. Claim 34,37,39,42,43,50, drawn to a method for administering cells and an organic therapeutic, classification depends on structure of organic therapeutic.
- X. Claims 35-36,39,42,43,50 drawn to a method for administering a PYY Therapeutic and an inhibitor, classification depends of structure of PYY Therapeutic and inhibitor.
- XI. Claims 35,36,39,42,43,50, drawn to method for administering a PYY antagonist and an inhibitor, classification depends of structure of PYY antagonist and inhibitor.

- XII. Claims 35,36,39,42,43,50, drawn to method for administering cells and an inhibitor, classification depends on structure of inhibitor.
- XIII. Claims 38,39,41,42,43,50, drawn to a method for identifying a PYY-affecting agent comprising administering agent and measuring effect compared to PYY or agonist, classification depends on structure of agent.
- XIV. Claims 40,50 drawn to a method for screening a DNA library classified in class 435, subclass 6.
- XV. Claims 44,50 drawn to a method for administering an antagonist which is antisense, classified in class 514, subclass 44.
- XVI. Claims 44,50 drawn to a method for administering an antagonist which is a ribozyme, classified in class 536, subclass 24.5.
- XVII. Claim 44,50 drawn to a method for administering a small organic molecule, classification depends on structure of small organic molecule.
- XVIII. Claims 44,50 drawn to a method for identifying a PYY-affecting agent using antisense, classification depends on structure of the antisense antagonist of PYY.
- XIX. Claims 44,50 drawn to a method for identifying a PYY-affecting agent using a ribozyme, classification depends on structure of the ribozyme antagonist of PYY.
- XX. Claims 44,50 drawn to a method for identifying a PYY-affecting agent using a small organic molecule, classification dependent upon structure of a small organic molecule antagonist of PYY.

XXI. Claim 47, drawn to a mature islet or β cell, classified in class 435, subclass 325.

XXII. Claim 48, drawn to a composition comprising an agonist, classification dependent upon structure of agonist.

XXIII. Claim 48, drawn to composition comprising an antagonist, classification dependent upon structure of antagonist.

XXIV. Claim 49, drawn to a transgenic non-human animal expressing an antagonist PYY polypeptide, classified in class 800, subclass 13.

XXV. Claim 49, drawn to a transgenic non-human animal with a disruption of a gene encoding a PYY Therapeutic, classified in class 800, subclass 21.

3. Inventions XII, XIII (product) and invention III, V, VIII, XI, XIII, XV, XVI (process of use) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case both the agonist and antagonist can be used in a different process of use such as receptor binding studies. In addition islet or β cells (invention XXI) can be used in a different process of use from the instant methods (invention I, II, III, VI, IX, XII) such as isolating endogenous proteins from whole cell extracts.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.05 for inventive groups that are directed to different

methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Each method (of Groups I-XX) recites structurally and functionally distinct elements, are not required one for the other, and achieve different goals.

5. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.06 for inventive groups that are directed to different products, restriction is deemed to be proper because the products of Groups XXI-XXV constitute patentably distinct inventions and are not required for each other.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate search requirements, and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper. A search and examination of all the groups in one patent application would result in an undue burden, because the searches for these groups are not co-extensive, the classification is different, and the subject matter is divergent.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD

RMD
December 7, 2000

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER